DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-033/S-018

Novartis Pharmaceuticals Corporation
Attention: Mr. Carl Schlotfeldt
59 Route 10
East Hanover, NJ 07936-1080

Dear Mr. Schlotfeldt:

Please refer to your supplemental new drug application dated August 7, 2000. This application was submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lotensin HCT (benazepril hydrochloride/hydrochlorothiazide USP) Tablets.

We acknowledge receipt of your submission dated July 18, 2001. Your submission of July 18, 2001 constituted a complete response to our April 13, 2001 action letter.

This supplemental new drug application provides for final printed labeling revised under **PRECAUTIONS/Geriatric Use** by adding information regarding renal function in the elderly, as follows:

> Of the total number of patients who received Lotensin HCT in U.S. clinical studies of Lotensin HCT, 19% were 65 or older while about 1.5% were 75 or older. Overall differences in effectiveness or safety were not observed between these patients and younger patients, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.
>
> Benazepril and benazeprilat are substantially excreted by the kidney. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert included in your July 18, 2001) submission. Accordingly, the supplemental application is approved effective on the date of this letter.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact:

Ms. Sandra Birdsong
Regulatory Project Manager
(301) 594-5312

Sincerely,

{See appended electronic signature page}

Raymond J. Lipicky, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Raymond Lipicky

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